

INTERNATIONAL SEARCH REPORT

International Application No
PCT/JP2004/014438

A. CLASSIFICATION OF SUBJECT MATTER
IPC 7 C12Q1/68 C12N9/10

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 7 C12Q C12N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, BIOSIS, EMBASE, WPI Data, PAJ

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|---|--|
| X | US 2003/104418 A1 (ZHANG CHAO ET AL) 5 June 2003 (2003-06-05) abstract page 4, left-hand column, paragraph 5 | 1-38, 41-48, 51-54, 56-58, 60-70, 73-75 |
| X | US 2003/157544 A1 (GISH KURT C ET AL) 21 August 2003 (2003-08-21) abstract page 1, right-hand column, paragraph 6 page 2, right-hand column, paragraphs 2,3 -/-- | 1-38, 41-48, 51-54, 56-58, 60-70, 73-75 |

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

* Special categories of cited documents:

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- *Z* document member of the same patent family

Date of the actual completion of the international search

24 February 2005

Date of mailing of the international search report

08.08.2005

Name and mailing address of the ISA

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|---|--|
| X | <p>ADAM PAUL J ET AL: "Arylamine N-acetyltransferase-1 is highly expressed in breast cancers and conveys enhanced growth and resistance to etoposide in vitro."</p> <p>MOLECULAR CANCER RESEARCH, vol. 1, no. 11, September 2003 (2003-09), pages 826-835, XP002317345 ISSN: 1541-7786 abstract page 827, left-hand column, last paragraph page 829, right-hand column, paragraph 1 page 831, left-hand column, paragraph 2</p> | <p>1-38, 41-48, 51-54, 56-58, 60-70, 73-75</p> |
| X | <p>PEROU C M ET AL: "Molecular portraits of human breast tumours"</p> <p>NATURE, MACMILLAN JOURNALS LTD. LONDON, GB, vol. 406, no. 6797, 17 August 2000 (2000-08-17), pages 747-752, XP002203006 ISSN: 0028-0836 abstract page 750; figure 3</p> | <p>1-38, 41-48, 51-54, 56-58, 60-70, 73-75</p> |
| X | <p>GEYLAN Y S ET AL: "Arylamine N-acetyltransferase activities in human breast cancer tissues"</p> <p>NEOPLASMA (BRATISLAVA), vol. 48, no. 2, 2001, pages 108-111, XP008027627 ISSN: 0028-2685 abstract page 110, right-hand column, line 4 - line 10</p> | <p>32-38, 41-48, 51-54</p> |
| A | <p>SGROI D C ET AL: "IN VIVO GENE EXPRESSION PROFILE ANALYSIS OF HUMAN BREAST CANCER PROGRESSION"</p> <p>CANCER RESEARCH, AMERICAN ASSOCIATION FOR CANCER RESEARCH, BALTIMORE, MD, US, vol. 59, no. 22, 15 November 1999 (1999-11-15), pages 5656-5661, XP000994514 ISSN: 0008-5472 cited in the application the whole document</p> | <p>1-38, 41-48, 51-54, 56-58, 60-70, 73-75</p> |

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C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category * | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|------------|---|--|
| A | DRESSMAN MARLENE A ET AL: "Gene expression profiling detects gene amplification and differentiates tumor types in breast cancer." CANCER RESEARCH, vol. 63, no. 9, 1 May 2003 (2003-05-01), pages 2194-2199, XP002317347 ISSN: 0008-5472 cited in the application the whole document ----- | 1-38, 41-48, 51-54, 56-58, 60-70, 73-75 |

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Box II Observations where certain claims were found unsearchable (Continuation of item 2 of first sheet)

This International Search Report has not been established in respect of certain claims under Article 17(2)(a) for the following reasons:

1. ☒ Claims Nos.: 39, 40, 49, 50, 55, 59, 71, 72, 76, 88, and 94
because they relate to subject matter not required to be searched by this Authority, namely:
Although claims 32 to 38, 41 to 48, 51, 65 to 70, 73, and 89 to 93 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.
2. ☒ Claims Nos.: 39, 40, 49, 50, 55, 59, 71, 72, 76, 88, and 94
because they relate to parts of the International Application that do not comply with the prescribed requirements to such an extent that no meaningful International Search can be carried out, specifically:
see FURTHER INFORMATION sheet PCT/ISA/210
3. ☐ Claims Nos.:
because they are dependent claims and are not drafted in accordance with the second and third sentences of Rule 6.4(a).

Box III Observations where unity of invention is lacking (Continuation of item 3 of first sheet)

This International Searching Authority found multiple inventions in this International application, as follows:

see additional sheet

1. ☐ As all required additional search fees were timely paid by the applicant, this International Search Report covers all searchable claims.
2. ☐ As all searchable claims could be searched without effort justifying an additional fee, this Authority did not invite payment of any additional fee.
3. ☐ As only some of the required additional search fees were timely paid by the applicant, this International Search Report covers only those claims for which fees were paid, specifically claims Nos.:
4. ☒ No required additional search fees were timely paid by the applicant. Consequently, this International Search Report is restricted to the invention first mentioned in the claims; it is covered by claims Nos.:
1-38 (partially), 41-48 (partially), 51-54 (partially), 56-58 (partially)
60-70 (partially), 73-75 (partially)

Remark on Protest

- ☐ The additional search fees were accompanied by the applicant's protest.
- ☐ No protest accompanied the payment of additional search fees.

FURTHER INFORMATION CONTINUED FROM PCT/ISA/ 210

This International Searching Authority found multiple (groups of) inventions in this international application, as follows:

Inventions 1-388: Claims 1-38 (partially), 41-48 (partially), 51-54 (partially), 56-58 (partially), 60-70 (partially), 73-75 (partially)

Methods and means for diagnosing breast cancer, and medical uses involving one of the 388 different known genes mentioned in claims 2 and 4.

Invention 389: Claims 77-87 (partially), 89-93 (partially), 95-97 (partially)

Methods and means for predicting breast cancer metastasis, and medical uses involving one of the 34 different known genes mentioned in claim 77.

Continuation of Box II.1

Although claims 32 to 38, 41 to 48, 51, 65 to 70, 73, and 89 to 93 are directed to a method of treatment of the human/animal body, the search has been carried out and based on the alleged effects of the compound/composition.

Continuation of Box II.2

Claims Nos.: 39, 40, 49, 50, 55, 59, 71, 72, 76, 88, and 94

Present claims 39, 40, 49, 50, 55, 59, 71, 72, 76, 88, and 94 relate to the medical use of candidate compounds defined only by reference to a desirable characteristic (e.g., the ability to suppress the biological activity of one of the gene products used in a screening method). The claims cover the medical use of all compounds having this characteristic or property, whereas the application provides support within the meaning of Article 6 PCT and/or disclosure within the meaning of Article 5 PCT for not a single of such compounds. In the present case, the claims so lack support, and the application so lacks disclosure, that a meaningful search is impossible. Independent of the above reasoning, the claims also lack clarity (Article 6 PCT). An attempt is made to define the methods/medical uses by reference to a result to be achieved. Again, this lack of clarity in the present case is such as to render a meaningful search impossible.

The applicant's attention is drawn to the fact that claims relating to inventions in respect of which no international search report has been established need not be the subject of an international preliminary examination (Rule 66.1(e) PCT). The applicant is advised that the EPO policy when acting as an International Preliminary Examining Authority is normally not to carry out a preliminary examination on matter which has not been searched. This is the case irrespective of whether or not the claims are amended following receipt of the search report or during any Chapter II procedure. If the application proceeds into the regional phase before the EPO, the applicant is reminded that a search may be carried out during examination before the EPO (see EPO Guideline C-VI, 8.5), should the problems which led to the Article 17(2) declaration be overcome.

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Information on patent family members

International Application No

PCT/JP2004/014438

| Patent document cited in search report | Publication date | Patent family member(s) | Publication date |
|---|---------------------|----------------------------|---------------------|
| US 2003104418 | A1 | 05-06-2003 | NONE |
| US 2003157544 | A1 | 21-08-2003 | NONE |